## **REMARKS**

## I. Status of the Application

Claims 1-23, 25-35, 37-51 and 53-72 are pending in the application. Claims 1-23, 25-33, 37, 45-50, 55 and 56 are withdrawn. Claims 34, 35, 38-44 and 58-66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over European Patent No. 0 099 167 to Yapp ("Yapp"). Claims 51, 53, 54, 57 and 67-72 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,571,203 to Masini ("Masini").

Applicants respectfully request reconsideration of the application in view of the following remarks.

## II. Claims 34, 35, 38-44 and 58-66 Are Patentable Over Yapp

Claims 34, 35, 38-44, and 58-66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yapp. This rejection is respectfully traversed.

Yap fails to disclose or make obvious a fastening element having a pin extending from a supporting element, with the pin having a longitudinal axis that extends at an angle of between about 125° and about 145° with respect to the bottom surface of the supporting element, as required by independent claim 34. Yapp also fails to disclose or make obvious a fastening element with a pin extending from a first side of a support element at an angle greater than 90° with the first side, as required by independent claim 59.

The Office Action acknowledges that Yapp does not disclose an angle between the longitudinal axis of the pin and the bottom surface of the supporting element of between about 125° and about 145°, but asserts that the required angle would have been obvious to one skilled

in the art, stating that discovering the optimum or workable ranges involves only routine skill in the art.

This assertion in the Office Action is not supported by the disclosure of Yapp, and, in fact, Yapp teaches away from such an angle. As noted in the Office Action, the angle between the longitudinal axis of the pin and the bottom surface of the plate is 90° in Yapp. Shaft 13 extends linearly from the neck 16 through the femur and emerges from the lateral cortex 19 just below the trochanter. (Yapp, page 4, lines 14-17). Bolt 28 is threaded into shaft 13 to hold it in this desired location. "A broad, shallow depression 46 is rounded from the exterior of the lateral cortex 19 just below the trochanter 38 to provide food seating and ingrowth into the porous interior surface of a grommet or washer 47", through which bolt 28 extends. (Yapp, page 4, lines 32-34.)

If the angle between the pin and the plate of Yapp were greater than 90°, let alone between about 125° and about 140°, the shaft 13 of Yapp would extend further down into the femur, and would not exit the femur in the desired position, that is, "just below the trochanter 38." Consequently, it can be seen that Yapp actually teaches away from the required angle of between about 125° and about 145°, as required by independent claim 34. Contrary to the assertion in the Office Action, the required angle of greater than 90° and the required range of between about 125° and about 145° would be neither "optimum or workable ranges" as applied to Yapp. An angle greater than 90°, and especially one between about 125° and about 145°, would simply not work in the fastener of Yapp. Such a large angle would not allow the bolt 28 and washer 47 to be located in the desired position just below the trochanter.

Thus, one skilled in the art would have no motivation or suggestion to modify the teachings of Yapp to have its shaft 13 extend at an angle greater than 90°, let alone between

about 125° and about 145°, with respect to flange 24. To do so would fly in the face of the teachings of the advantages of Yapp.

Further, there is no motivation or suggestion for one skilled in the art to modify Yapp to provide a coupling element offset with respect to the longitudinal axis of the pin, as required by claims 39 and 58, 59. As seen in Fig. 7 of Yapp, terminal 84 and neck 32 are axially aligned with the shaft 13. There is simply no *prima facie* case of obviousness presented in the Office Action to modify this relationship.

Accordingly, the rejection is improper and should be withdrawn.

## III. Claims 51, 53, 54 57 and 67-72 Are Patentable Over Masini

Claims 51, 53, 54-57 and 67-72 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Masini. This rejection is respectfully traversed.

Masini fails to disclose or make obvious a method for fastening an implant including the step of forming an abutment surface that extends approximately at right angles to the load axis of the joint, as required by independent claims 51 and 67.

In Masini, the femur is sawn on cut line 230, which extends at a right angle to the longitudinal axis 234 of the femur. This abutment surface formed in Masini is not a right angle with respect to the load axis of this joint. As can be seen in Fig. 1A of the present invention, and described at page 7, line 29 through page 8, line 2, the load axis is a straight line drawn through the center of the hip head and the intercondylar space of the knee. The load axis is not parallel with the longitudinal axis of the femur. Rather, it usually includes an angle between 6° and 12°.

Consequently, since the abutment surface of Masini is at a right angle to the longitudinal axis 234 of the femur, it cannot be at a right angle to the load axis of the joint.

Further, as noted in the Office Action, Masini fails to disclose or make obvious a pin driven into a bone at an angle of between about 125° and about 145° with respect to the abutment surface, as required by independent claim 51. Masini also fails to disclose or make cementing a fastening element into a hole with a pin extending from a first side of a support element at an angle greater than 90° with the first side, as required by independent claim 67.

The Office Action acknowledges that Masini does not disclose an angle between the longitudinal axis of the pin and the bottom surface of the supporting element of between about 125° and about 145°, but asserts that the required angle would have been obvious to one skilled in the art, stating that discovering the optimum or workable ranges involves only routine skill in the art.

There is no motivation or suggestion for one skilled in the art to modify the angle of pin 312 of fastening element 442 to extend at the required angle. If the angle between the pin 312 and the support element 226 were greater than 90°, and especially if it were between about 125° and about 145°, the fins 310 on pin 312 would extend into the cortex. Masini expressly teaches away from such a result. Specifically, Masini states that it is important to "ensure that ... the fins remain within the softer candellous bone, and do not invade the cortex, which might crack under the forces associated with installation." (col. 6, lines 6-10).

Consequently, it can be seen that Masini actually teaches away from the required angle of greater than 90° and the required range of between about 125° and about 145°. An angle greater than 90°, and especially one between about 125° and about 145°, would simply not work in the fastener of Masini.

Additionally, there is no motivation or suggestion for one skilled in the art to modify Masini to provide a coupling element offset with respect to the longitudinal axis of the pin, as

required by claims 57 and 67. There is simply no prima facie case of obviousness presented in

the Office Action to modify this relationship.

With respect to claim 53, Applicant respectfully points out that Masini does not disclose

or make obvious a pin driven into a bone such that a longitudinal axis of the pin extends

approximately parallel to the longitudinal axis of the neck. Rather, the axis of the pin of Masini

extends parallel to the longitudinal axis of the femur itself.

Accordingly, for these reasons the rejection is improper and should be withdrawn.

IV. <u>CONCLUSION</u>

Reconsideration and allowance of all the pending claims is respectfully requested. If a

telephone conversation with Applicant's attorney would expedite prosecution of the above-

6

identified application, the Examiner is urged to call the undersigned at (617) 720-9600.

The Commissioner is hereby authorized to charge any additional fees or credit

overpayment to Deposit Account No. 19-0733.

Respectfully submitted,

Dated: August 29, 2005

Gregory J. Cohan, Reg. No. 40,959

BANNER & WITCOFF, LTD.

28 State Street, 28th Floor

Boston, MA 02109

(617) 720-9600

USSN 10/037,318 Express Mail Receipt No. EV 641 701 446 US